MAY 19 2011

No. 10-1177

IN THE

Supreme Court of the United States

WYETH LLC AND WYETH PHARMACEUTICALS, INC.,
Petitioners,

v.

JERALDINE SCOFIELD, *ET AL.*
Respondents

On Petition For a Writ of Certiorari to the Supreme Court of Nevada

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

The Questions Presented, properly related, are:

1. When a trial court's conclusion that the jury's verdicts suggest passion and prejudice is merely a factor in its finding of excessiveness—but does not entail a determination that the jury abandoned its neutrality—and when it is the defendant itself who moves for remittitur on the ground that such relief would cure any such passion and prejudice, does due process nonetheless require the trial court to grant a new trial instead of remittitur?

2. Where the compensatory damages are significant, is the ratio between compensatory and punitive damages the conclusive and overriding guidepost as to the reasonableness of a punitive damages verdict, regardless of the facts and circumstances?

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BRIEF FOR RESPONDENTS IN OPPOSITION

Plaintiffs-Respondents Jeraldine Scofield, Wendell Forrester as special administrator of the estate of Pamela Forrester, and Jeffrey Ouelette and Richard Rowatt as special administrators of the estate of Arlene Rowatt respectfully submit this brief in opposition to the petition for a writ of certiorari.

COUNTERSTATEMENT OF THE CASE

The Petition's breezy, four-paragraph description of Wyeth's decades-long development, research, and marketing of its hormone therapy drugs omits key facts, making it difficult for the reader to understand how the jury in this case could have found Petitioners [hereinafter "Wyeth"] liable for Respondents' cancers, or that Wyeth engaged in egregious misconduct. Accordingly, Respondents provide a fuller accounting here, drawn largely from the Nevada Supreme Court's balanced summary of the evidence presented at trial. Pet. App. 6a-14a. That evidence confirms that Wyeth intentionally undermined and hid the mounting scientific evidence that its hormone therapy drugs caused breast cancer, refused to follow up on dozens of safety signals with much needed breast cancer studies, did so with a reckless disregard for the health of its consumers, pursued this course of conduct with an objective of significant financial gain, and, as a result, severely injured these three Nevada women.

A. Facts as Described by the Nevada Supreme Court

In 2004, Plaintiffs Jeraldine Scofield, Pamela Forrester, and Arlene Rowatt, residents of Nevada, sued Wyeth after being diagnosed with breast

cancer.[1] These personal injury and strict products liability suits, which were consolidated for trial, alleged that these women developed breast cancer due to their use of Wyeth's combination hormone therapy drug. That drug therapy consisted of estrogen taken together with a synthetic progestin (collectively, "E+P"). E+P is prescribed to relieve menopausal symptoms, such as hot flashes and vaginal atrophy and to prevent osteoporosis. E+P could be taken as either two pills or, after 1995, in a single Wyeth drug called "Prempro."

Wyeth first introduced estrogen (or Premarin) in 1942, before the Food and Drug Administration (FDA) had authority to fully evaluate drug safety and efficacy. Premarin was thus a "grandfathered" drug and did not have to meet current FDA approval standards.

In the mid-1970s, Wyeth's estrogen sales plummeted after it was shown that estrogen use caused endometrial cancer. Wyeth thus started recommending the addition of progestin to curb estrogen's risk of endometrial cancer. Respondents were all prescribed E+P.

Internal corporate documents demonstrate that, by 1976, Wyeth knew that a specific type of breast cancer (hormone dependent cancers) can and does respond to the presence of hormone drugs. All three women developed this type of breast cancer, a cancer that requires hormones to develop and grow.

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[1] After trial, Forrester and Rowatt died of causes unrelated to this litigation. The administrators of their estates were substituted as parties and appear here as respondents, along with Plaintiff-Respondent Scofield.

Rather than conduct studies to prove the safety of using E+P together, Wyeth instead requested FDA approval to sell these two "grandfathered" drugs together to treat menopause. The FDA rejected Wyeth's application and specifically told Wyeth that the company first needed to conduct studies to confirm the combination drug's safety. Over the next fifteen years, Wyeth was put on notice—more than a dozen times—by its own scientists, the FDA, and independent researchers that there were unanswered question about the breast cancer risk of E+P. Wyeth's own scientists opined that the number of E+P studies were "practically non existent." In 1990 and again in 1991, a panel of FDA experts reviewed the worldwide literature and found insufficient data to determine whether E+P increased the breast cancer risk. Wyeth celebrated these findings while failing to budget even a single dollar for breast cancer research. Internal corporate documents reveal that Wyeth was afraid that the results of such an E+P study could be "embarrassing." Wyeth's documents also confirm a corporate policy to not fund breast cancer studies on E+P.

Outside of Wyeth, independent researchers started reporting increased breast cancer risk with E+P. One study, published in the New England Journal of Medicine in 1989, showed a relative risk of 4.4 (a 4-fold increased risk) of breast cancer in E+P users, In response to this scientific data, Wyeth instructed its sales force not to discuss the study with any prescribing physicians. On multiple occasions from 1990 through 2000, when independent researchers expressed concern about E+P's breast cancer risk, rather than publicize those results to the doctors and patients, Wyeth instead

created internal taskforces charged with counteracting these findings, dismissing the results, and downplaying the breast cancer risk of its drugs.

For example, in 1996, a study revealed that E+P particularly increased the risk of breast cancer for thin or lean women. Jeraldine Scofield is a very thin woman. Rather than warn physicians, Wyeth instead created the "Breast Cancer Working Group" which was tasked with keeping the article "confidential" and warned not to discuss the study outside the company. Wyeth also developed a detailed public relations strategy to minimize and divert media attention from the study. More alarming, Wyeth updated its European warning label to describe this accelerated risk for a specific population of users, but never updated the American label.

Wyeth responded to emerging concerns about its drugs with public relation campaigns that provided reassurance of the drugs' safety as well as scathing criticism of each study and its authors. Wyeth took steps to neutralize critics, counter negative publicity with positive press and agreed to fund educational organizations only if they first committed to saying that E+P did not cause breast cancer. Wyeth management approved a $40.4 million marketing budget to counter rising awareness about safety issues with E+P. Wyeth also began to promote these drugs for unproven and unsupported heart and mental health benefits. In television ads, textbooks, and information pamphlets, Wyeth encouraged long-term E+P use for illusory cardiac and cognitive protection benefits that were later proven false. The FDA repeatedly admonished Wyeth for its promotion

of unapproved benefits, but the company continued its marketing efforts anyway.

Wyeth also "ghost-wrote" dozens and dozens of published medical articles that downplayed the risk of breast cancer and promoted unproven heart and brain benefits of these drugs. Even though the idea for the articles was Wyeth's and Wyeth hired non-physician technical writers to actually write them, Wyeth's role in the creation of these articles was not revealed. The published papers appeared to be authored by independent physicians.

Despite the lack of safety studies, and in the face of emerging science showing significant safety issues with E+P, Wyeth recommended E+P use for "all women for life" in their promotional materials.

In 1994, the FDA granted Wyeth conditional approval of a single E+P pill (Prempro). This conditional approval required Wyeth to conduct a "comprehensive investigation" of the breast cancer risk. Despite that requirement, Wyeth never conducted a breast cancer study.

In 2002, the world uncovered the truth about hormone therapy. The National Institutes of Health conducted a large, long-term study to assess the benefits and risks of E+P. This study, the Women's Health Initiative (WHI), was prematurely halted in 2002 due to an increase in invasive breast cancer in the E+P users. The breast cancer results crossed the study's pre-determined safety index, and the NIH had to stop the study prematurely to protect the volunteers. The WHI study also showed no heart or brain benefit, but rather an increase in cardiac events and clinically meaningful cognitive decline.

After this data was made public, prescriptions for E+P fell dramatically, by as much as 80 percent. The number of hormone dependent breast cancers in this country also fell for the first time. Respondents' expert epidemiologist testified, based upon published epidemiological studies, that E+P caused approximately 8,000 to 15,000 additional breast cancers each year. This statistic was appropriately introduced as evidence of general causation as well as of Wyeth's reprehensibility under this Court's guidance in *Phillip Morris USA, Inc. v. Williams*, 549 U.S. 346, 355 (2007).

After the WHI, Wyeth brought a new drug to market called Low Dose Prempro. This new drug has significantly less E and P, is recommended only for short duration use, and is a second-line treatment. Today, these drugs carry a black-box warning, the strongest FDA warning possible, which confirms that use of E+P increases the risk of invasive breast cancer and that the risk increases with each year of use.

Respondents Rowatt, Scofield, and Forrester all ingested E+P long-term: Rowatt for more than seven years; Forrester for nine; and Scofield for fifteen.

Each testified at trial about the horrific effect of breast cancer on their lives, and their families'. This included testimony about the women's various surgeries, substantial resulting disfigurement, and post-surgical treatments, including chemotherapy and radiation. Each testified that they would not have taken the medication had they known of the risk of breast cancer. Their health care providers also testified that, when they prescribed Wyeth's

hormone therapy drugs to Respondents, they thought the benefits outweighed the risks and that there was no real risk of breast cancer from the drug. The physician's opinions and prescribing practices changed dramatically after the results of the WHI study were publicized.

The jury originally returned verdicts in Respondents' favor totaling $134.6 million in compensatory damages. Because the jury also found that Wyeth acted with malice or fraud, the district court informed the jury that it would return for a second phase on punitive damages. The district court later learned, before the start of the second phase, that the initial verdict mistakenly already included punitive damages. The district court thus proposed to reinstruct the jury and direct it to deliberate anew only as to compensatory damages. Wyeth originally agreed to this procedure, then changed its mind and requested a mistrial. The trial court denied Wyeth's motion and, following a second round of deliberations, the jury returned compensatory verdicts in Respondents' favor totaling $35.1 million.

At the conclusion of the second punitive phase, the jury returned additional verdicts in Respondents' favor totaling $99 million. Wyeth moved for a judgment as a matter of law, a new trial, or remittitur. Wyeth's motion for remittitur invited the district court to remit the awards because they were, in Wyeth's view, excessive and the product of "passion and/or prejudice." The district court denied the first two requests, but granted Wyeth's remittitur motion. The court reduced the total compensatory damages for the three plaintiffs to $23

million[2] and the punitive damages to $57,778,909. It found that, as a matter of Nevada law, remittitur was appropriate because the compensatory and punitive damages awards were excessive suggesting passion and prejudice. Respondents accepted the remitted awards.

Petitioners appealed to the Nevada Supreme Court. In a unanimous decision, the court "perceive[d] no reversible errors in the issues raised on appeal" and thus affirmed the district court's judgment.

B. Facts Misstated by Wyeth in Its Petition

In a bid to make its Petition more compelling and to undermine the decision below, Wyeth repeatedly characterizes the determinations of the Nevada district court and supreme court as having concluded that the jury was inflamed by passion and prejudice *as a result of* improper conduct on the part of Respondents' counsel at trial. *See, e.g.*, Pet. 2-3, 8 & 16. The courts below made no such finding. Both the trial court and supreme court found no attorney misconduct justifying reversal. Instead, the trial court, as a matter of state law, determined that the jury's verdicts were excessive and stated that the amounts awarded "suggest[ed]" passion and

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[2] Wyeth incorrectly asserts that the compensatory damages awards in this case are greatly in excess of all other hormone therapy verdicts to date. Recently, a Pennsylvania jury returned a compensatory verdict of $6.3 million for a single plaintiff, a number right in line with the remitted awards here for three plaintiffs. *Kendall v. Wyeth*, No. 040600965 (Pa. Ct. Common Pleas Nov. 21, 2009).

prejudice. Pet. App 51a. The Supreme Court merely accepted the trial court's ruling on this issue. As explained *infra*, pp. 20-22, this category of suggested passion or prejudice stands on a very different legal plane than that which is engendered by attorney misconduct. Indeed, under Nevada law, passion and prejudice is a term of art used to describe one factor of excessiveness.

In contrast to Wyeth's assertions, *see* Pet. 3, the FDA did not approve of Wyeth's conduct in this case, and Prempro is not approved and still prescribed as it was when taken by Respondents. Indeed, the FDA repeatedly admonished Wyeth for its inappropriate marketing and consistently warned Wyeth that studies were needed to answer outstanding safety issues with E+P. Wyeth steadfastly ignored the FDA. Indeed, Wyeth actively downplayed the risks of E+P while exaggerating the unproven benefits, a course of conduct the Nevada Supreme Court described as "fraught with reprehension and deception." Pet. App. 28a. Today the FDA requires strong, definitive warnings about the breast cancer risk in a black box warning. And new Low Dose Prempro is used only short term for second line treatment.

REASONS FOR DENYING THE PETITION

The Petition fails to satisfy any of the traditional bases for this Court's review. *See* Sup Ct. R. 10. The Petition provides a woefully incomplete account of both the material procedural history of this case and the record evidence. Contrary to the tale Wyeth spins, the record—and the unanimous opinion of the Nevada Supreme Court—tells the story of a company that resisted obligations imposed

by the FDA, that undertook extensive campaigns to provide false reassurance that its drugs were safe while unlawfully promoting off-label uses, and that received the relief it specifically sought from the trial court, a remittitur. It is a record that provides no basis to review the questions Wyeth seeks to present.

By representing to the courts below that a remittitur, if granted, would provide sufficient relief, Wyeth is ill-positioned to now argue that this relief violated Wyeth's constitutional rights. Wyeth's Petition, in essence, asks this Court to find that a court violates a party's Due Process rights when the party receives the relief it successfully requested.

Moreover, Wyeth's question on the need for a new trial rather than remittitur fails to present an important federal question on which the lower courts are in conflict, or about which they may be fairly said to be confused. That lack of conflict is true with regards to both questions presented. whether remittitur violated due process and whether the punitive damages must be reduced from 1.5:1 to 1:1. Thus, the petition should be denied.

I. THE FIRST QUESTION IS NOT PROPERLY BEFORE THE COURT

A. Wyeth Requested, and Received, the Very Relief It Now Insists Is Constitutionally Deficient

Post-trial, Wyeth sought relief from the jury's entire verdict by moving for a new trial or, alternatively, for a remittitur. The trial court granted Wyeth's request for a substantial remittitur, albeit not to the extent requested by Wyeth. Now,

Wyeth asks this Court to relieve it from the relief it sought and received.

This Court should deny the Petition and adhere to its longstanding practice of declining to review invited errors that were not raised and passed upon below.[3] *See Springfield v. Kibbe*, 480 U.S. 257, 259-60 (1987) (per curiam), *Minneapolis & St. L. R. Co. v. Winters*, 242 U.S. 353, 355, 356 (1917) (Holmes, J.) (holding that any error in basing personal injury recovery upon a federal statute cannot be urged where defendant "invoked and relied upon that statute" because a party "cannot complain of a course to which it assented below."); *McGillin v. Bennett*, 132 U.S. 445, 452-53 (1889) (holding that a party cannot predicate error on the admission of evidence he himself introduced).

In *Springfield*, for example, the petitioner did not object at trial to a jury instruction stating that proof of gross negligence would suffice to establish a municipality's liability under federal law. 480 U.S. at 259. In fact, the petitioner proposed its own instruction to the same effect. *Id.* Later, before this Court, petitioner for the first time argued for a higher standard than gross negligence. The Court dismissed the writ as improvidently granted, relying upon the "considerable prudential objection to reversing a judgment because of an instruction that petitioner accepted, and indeed itself requested." *Id.* That same prudential objection strongly militates

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[3] This discussion assumes only for purposes of argument that there was error. For the reasons discussed below, however, there was no error because remittitur was constitutionally acceptable relief under these circumstances

against this Court's review of Wyeth's first question, because it would require the Court to reverse a judgment based on relief that Wyeth appropriately requested *and received*.

Before this Court, Wyeth argues that, as a matter of due process, a new trial is the "only" constitutionally acceptable remedy when a verdict may be the product of a jury's passion or prejudice. Pet. 18. According to Wyeth's new view, remittitur is never a constitutionally appropriate remedy where, as here,[4] the verdict may be a product of passion and prejudice and may have affected the jury's decision on liability. Pet. 3, 15-16.

But in the trial court, Wyeth specifically requested that the court remit the award for compensatory and punitive damages if it did not order a new trial. App. 2a (Wyeth's motion requesting remittance of the punitive and future compensatory damages to zero and past compensatory damages to a "fair" and "reasonable" amount). Remittitur *was* appropriate, Wyeth told the trial court, *because* the award was "excessive" and "clearly the result of passion and/or prejudice." App. 2a. That is the converse of Wyeth's current argument—that remittitur *was not* appropriate

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[4] Respondents dispute that the verdict was infected with "passion and prejudice" in a due-process sense. However, as explained at the tail-end of section I.B (pp. 17-18) and in section III.A, the term passion and prejudice in some jurisdictions, including Nevada, "does not entail a determination that the jury has abandoned its neutrality; it is merely a finding of excessiveness." PLAC Amicus Br. Supp. Pet 11.

because the award was the result of passion and prejudice. Pet. 15-16.

The analysis does not change merely because Wyeth sought remittitur as alternative relief to a new trial. It never argued that only a new trial could cure a verdict affected by passion and prejudice. Wyeth requested remittitur in the alternative on the basis of the reasoning Wyeth now opposes, that remittitur is sufficient to cure an excessive verdict considered evidence of passion or prejudice. After asserting that relief to be sufficient before the trial court, reaching the first question presented here would appear to "excuse inattention or reward cunning." *United States v. Wells*, 519 U.S. 482, 489 (1997).

B. The Courts Below Never Addressed Petitioners' Novel Due Process Argument

The prudential objection assumes added force here because the Nevada courts never addressed Wyeth's novel due-process argument and were deprived of a fair opportunity to do so. *See Wells*, 519 U.S. at 489 (recognizing that the Court may, in its discretion, review invited error if it was pressed or passed on in the courts below). Review of the first question presented therefore would be inappropriate.[5]

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[5] This is the case even if the requirement that a federal claim be addressed or properly presented in state court is prudential rather than jurisdictional. *See Adams*, 520 U.S. at 90.

With few exceptions, this Court has "adhered to the rule in reviewing state court judgments under 28 U.S.C. § 1257 that [it] will not consider a petitioner's federal claim unless it was either addressed by, or properly presented to, the state court that rendered the decision we have been asked to review." *Adams v. Robertson*, 520 U.S. 83, 86 (1997). *Adams* makes clear that when the highest state court is silent on petitioner's federal claim, this Court assumes that the issue was not properly presented, *id.*, unless Petitioner "demonstrat[es] that the state court had 'a fair opportunity to address the federal question that is sought to be presented here.'" *Id.* at 87 (citing *Webb v. Webb*, 451 U.S. 493, 501 (1981)).

The Nevada Supreme Court in this case did not squarely address Wyeth's novel due process argument and this Court should thus assume that the issue was not properly presented. What is more, Wyeth cannot defeat this assumption because, as a careful review of the briefing in the lower courts confirms, the courts below did not have a fair opportunity to address the specific due-process question that Wyeth now presents.

The Nevada Supreme Court never discussed whether, as a matter of due process, the "only" constitutionally acceptable remedy when a verdict has been tainted by a jury's passion or prejudice is a new trial. *See* Pet. App. 39a-44a. Although Wyeth attempts to locate its due-process argument in the court's discussion of whether "the jury improperly deliberated and awarded punitive damages without receiving proper instructions," thereby violating Petitioners' "purported procedural due process"

rights, Pet. App. 41a, the issue cannot fairly be said to be situated there.

After concluding that the district court had properly bifurcated proceedings and instructed the jury on liability and compensatory and punitive damages, the Nevada Supreme Court discussed whether remittitur cured the jury's premature deliberations on *punitive damages*. *See id.* at 41a, 43a. Petitioners' current constitutional objection to remittitur, by contrast, is different in kind—that remittitur is constitutionally defective in any case where there is a finding of passion and prejudice because it does not address a jury's findings on *liability*. Pet. 15. At no point in its decision, did the Nevada Supreme Court consider whether passion and prejudice also tainted the jury's findings on liability, and whether remittitur would be constitutionally inappropriate in that circumstance, confirming that the issue was never properly presented to that court.

Furthermore, the court discussed only whether, *as a matter of state law*,[6] remittitur cured excessive compensatory and punitive damages.[7] Pet.

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[6] The Court did also, however, review the punitive damage award for gross excessiveness under the standard established in *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559 (1996), an issue relevant only to the second Question Presented. Pet App 39a-41a.

[7] Though Wyeth repeatedly trumpets that both courts below agreed that the jury's verdicts were the product of passion and prejudice due to an inflaming closing argument, neither court so concluded. Instead, by virtue of the size of the verdicts, the trial court found that the verdicts "suggest" passion and prejudice. Pet App. 51a When the trial court used

App. 3a, 33a, 43a. The court's standard of review makes that plain. The court reviewed the district court's decision to grant remittitur on the basis of an abuse of discretion standard. Pet. App. 43a (citing *Lehrer McGovern Bovis, Inc. v. Bullock Insulation, Inc.*, 197 P.3d 1032, 1037-38 (Nev. 2008)). That standard of review only applies to a suggestion of "passion and prejudice" in a state-law sense *See id.*; *see also Canterino v. The Mirage Casino-Hotel*, 16 P.3d 415, 417 (Nev. 2001). It does not apply where constitutional rights are at stake; because the proper standard then is *de novo* review. *See Callie v. Bowling*, 123 Nev. 181, 183, 160 P 3d 878, 879 (2007) ("This court applies a de novo standard of review to constitutional challenges."). The court's use of abuse-of-discretion review thus confirms that the Nevada Supreme Court did not consider the district court's remittitur to implicate constitutional rights.

Because the issue was never properly presented below, the Nevada courts never had a fair opportunity to address Wyeth's new due-process question. Certainly the district court had no such fair opportunity because Wyeth moved that court to *remit* the awards because of the jury's passion and prejudice. Consequently, it had no reason to even consider whether remittitur was constitutionally *inappropriate* in this circumstance.

Neither did the Nevada Supreme Court have a fair opportunity to consider this constitutional question. As a prudential matter, the Nevada court

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the phrase "passion and prejudice," it cited only to Nevada law. *See* Trial Court Order at 6 (citing *Harris v. Zee*, 486 P.2d 490 (1971)). The Nevada Supreme Court accepted the trial court's ruling. Pet. App. 43a

only considers issues raised in the trial court. *See Diamond Enters., Inc. v. Lau*, 951 P.2d 73, 74 (Nev. 1997). Accordingly, it could not have considered the objection Wyeth now presents to this Court.

Given Wyeth's failure to present, let alone preserve, the issue in the district court, the Nevada Supreme Court's silence on Wyeth's new federal due process claim is understandable. Further demonstrating the utter absence of this issue before the Nevada Supreme Court, an examination of Wyeth's briefing there reveals confusing and contradictory arguments that would lead a court to eschew the issue entirely. Although Wyeth, for the first time, argued in their briefing to the Nevada Supreme Court that a new trial was the only constitutionally acceptable remedy, Wyeth nevertheless also asked the Nevada Supreme Court to remit the awards further. Critically, Wyeth's request for remittitur implicitly, if not explicitly, suggested that remittitur *could* blanch the stain of passion and prejudice from the verdict *if* the remittance was sufficiently severe. In its opening brief, Wyeth stated, in a section entitled "The Remitted Awards Remain Excessive": "But even as remitted [by the district court], the awards *remain* grossly disproportionate to the injuries proven and preserve the taint of the jury's passion and prejudice." App. 4a (emphasis added). Wyeth's requested solution? Order a new trial *or* an additional remittitur of "each Plaintiff's compensatory award [remitted] to no more than $1 to 2 million each." App. 5a.

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It bears emphasis that strict adherence to the regular practice of refusing to review invited errors

or federal issues that lower state courts did not address and were deprived of a fair opportunity to address is especially warranted here. Moreover, comity requires it. As in *Adams*, "'it would be unseemly in our dual system of government' to disturb the finality of state judgments on a federal ground that the state court did not have occasion to consider," 520 U.S. at 90 (quoting *Webb v. Webb*, 451 U.S. 493, 500 (1997)—and indeed on a ground that Petitioners invited.

So, too, do practical considerations. Petitioners' failure to raise the issue in the trial court at all, and to raise it in a clear and non-contradictory manner in the Nevada Supreme Court, deprived the lower courts of an opportunity to create an adequate factual and legal record to assist this Court, should it choose to hear this issue. *See id.* at 90-91.

Had Petitioners properly presented their constitutional objection to remittitur, the high court would have engaged in *de novo* review, applicable when constitutional rights are at stake. *See supra* at 15. *De novo* review would have required the Nevada Supreme Court to distinguish between passion and prejudice in a state-law sense and in a constitutional sense. *Cf. Cooper Indus., Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424, 450 (2001) (Ginsburg, dissenting). The court, however, made no such finding. As a result, Wyeth is asking this Court to review *de novo* a different issue than the one that the Nevada Supreme Court reviewed for an abuse of discretion. That imbalance creates obvious practical difficulties, including the problem that this Court of final review would be the first appellate court to

engage in plenary review of Petitioners' novel due process rule.

Permitting a party, after both trial and appeal, to raise issues not fairly presented below after it has exhausted appeals in a State's court system undermines the orderly administration of justice, as well as fundamental precepts of fairness.

II. THERE IS NO CONFLICT CONCERNING THE QUESTION PRESENTED BECAUSE NO COURT HAS ADOPTED WYETH'S DUE PROCESS THEORY

Wyeth fails to identify a single decision holding that due process *requires* a new trial and *disallows* remittitur when a verdict is tainted by passion and prejudice. Instead, it attempts to extrapolate such a principle from cases that discuss nothing of the sort.

Wyeth relies heavily on *Minneapolis, St. Paul & Sault Ste. Marie Railway Co. v. Moquin*, 283 U.S. 520 (1931), *see* Pet. 11-12, 15, which is not a due process case. In *Moquin*, the Court considered whether a state trial court erred in failing "to grant a new trial in a case under the Federal Employers' Liability Act (45 USCA §§ 51-59) where the verdict was obtained by appeals to passion and prejudice." *Id.* at 521. The Court concluded that "[i]n actions under the federal statute no verdict can be permitted to stand which is found to be in any degree the result of appeals to passion and prejudice." *Id.* Thus, this Court's holding was limited to a particular federal statute being litigated in state court and a form of passion and prejudice engendered by the misconduct

of counsel.[8] The decision expressly noted that the federal common law rule it was announcing had no bearing on Minnesota procedures. *Id.* ("Whether under the state's jurisprudence the present record would entitle petitioner to a new trial or to such a conditional order [remittitur] as was awarded is immaterial.").

Lower federal court decisions cited by Wyeth also do not support its claim that there is a split on whether due process requires a new trial rather than remittitur under these circumstances. *See* Pet. 12. In some of the cited cases, state law simply required the application of such a rule, though not as a matter of due process. *See Mason v. Texaco, Inc.*, 948 F.2d 1546 (10th Cir. 1991) (applying Kansas law). In others, the reference to such a rule was *dictum* because the courts found no passion or prejudice. *E.g.*, *De Leon Lopez v. Corporacion Insular de Seguros*, 931 F.2d 116, 125 (1st Cir. 1991); *Earl v. Bouchard Transp. Co., Inc.*, 917 F.2d 1320, 1327 (2d Cir. 1990).

Similarly, the state court decisions Wyeth cites either adopt or reject a standard on when a new trial is warranted as a matter of state law, not federal due process. *See* Pet. 13 (collecting cases); *see also Kugling v. Williamson*, 42 N.W.2d 534, 539 & n.6 (Minn. 1950) ("Remittitur may not be applied in state courts where actions are based on federal *statutes*" (emphasis added)); *Wollersheim v. Church*

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[8] PLAC, in its amicus brief (at 4), traces this "principle" back to *Arkansas Valley Land & Cattle Co. v. Mann*, 130 U.S. 69 (1889), but, as PLAC itself concedes (at 5), the Court's discussion of what the proper course might have been had the jury in that case been influenced by passion and prejudice is *dicta*. *See* 130 U.S. at 75.

of Scientology, 6 Cal Rptr. 2d 532, 546 (Ct App. 1992) ("[T]here is no merit to Scientology's claim *Moquin* supersedes the many California Supreme Court and Court of Appeal cases which have reduced punitive damage awards rather than setting them aside after finding those awards were excessive and thus "presumed to be the product of passion and prejudice." (citation omitted)).

III. THIS IS NOT A PROPER VEHICLE FOR ADDRESSING WHAT IS OTHERWISE AN UNIMPORTANT ISSUE

A. The Courts Below Never Found that the Jury Abandoned Its Neutrality But Instead Concluded that There Was "Substantial Evidence" to Support the Verdicts

There is no finding by the lower courts that passion and prejudice infected the jury's findings on liability, or that the jury ever abandoned its neutrality. Wyeth's due-process argument depends on such a finding, and in its absence the due-process question is not duly presented.

In this case, the district court reviewed the jury's verdict based upon specific state law factors, found that the awards were excessive as a matter of state law and thus were presumed to be the product of passion and prejudice. *See* Pet. App. 45a (Trial Court Order at 6) (stating that the awards "suggest" passion and prejudice). This use of the term passion and prejudice, as PLAC observes in its amicus brief, "does not entail a determination that the jury has abandoned its neutrality; it is merely a finding of excessiveness." PLAC Br. 11. Although PLAC

assumes that this type of passion and prejudice does not apply to this case (*see* PLAC Br 2), it cites a federal district court decision applying Nevada law as an example of courts that "label any award they deem to warrant reduction as being the product of passion and prejudice—without regard to whether they have concluded that the jury actually departed from its required neutrality." PLAC Br. 10 (citing *Matlock v. Greyhound Lines, Inc.*, 2010 WL 3171262, at *1-*2 (D. Nev. 2010)).

PLAC is half-right: Nevada *is* a jurisdiction in which a determination of excessiveness suggests passion and prejudice but does not entail a finding that the jury abandoned its role as a neutral fact-finder. *See Matlock*, 2010 WL 3171262, at *1-*2. Contrary to Wyeth's and PLAC's submission, however, this *was* the sense in which the district court in this case used the phrase. Notably, *Matlock* cited *Harris v. Zee*, 486 P.2d 490 (1971), as authority for its understanding of the phrase "passion and prejudice" under Nevada law. 2010 WL 3171262, at *1. So too did the district court in this case cite *Harris* when it found that the verdicts "suggest" passion and prejudice. App. 7a & n.5 (Trial Court Order at 6). Clearly, then, the district court's finding that the verdicts in this case suggested passion and prejudice referred to excessiveness but did not entail a finding that passion and prejudice infected the jury's determination on liability or that the jury had abandoned its role as a neutral fact-finder.[9] In the

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[9] Wyeth offers contradictory accounts of the district court's findings. At one point, it tells this Court that the district court "seemingly assumed that the passion and prejudice had not tainted the jury's decision on liability." Pet 16 (emphasis removed). At another, it says that this is an excellent vehicle

absence of such a finding, this is not a proper vehicle for addressing Wyeth's due process question.

There is no fair basis to presume that passion and prejudice infected liability. The courts below both found "substantial evidence" to support the jury's findings on liability, damages and Wyeth's malice. Pet. App. 37a-39a; *see also id.* at 33a (finding "substantial evidence" of actual past and future damages). The lower courts did not believe, and there is no record support for the view, that the jury's decision on liability was without support in evidence or infected by passion and prejudice. Rather, the lower court's decisions prove the exact opposite.

B. State Courts Already Provide All the Process Defendants Are Constitutionally Due

Consideration by this Court is unnecessary because state courts already provide defendants with ample opportunity to contest compensatory and punitive damages liability and to contest the reasonableness of a damages judgment. Wyeth had that opportunity here; they were permitted to, and did, move for both a new trial and remittitur. That procedure was fairly applied below.

There is also significant reason to doubt the correctness of Wyeth's understanding of due process. No court has ever held that the substantive (or procedural) guarantees of due process require a new

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because there is "no doubt" that passion and prejudice infected all of the jury's decisions as the "trial court so found." *See* Pet. 17.

trial whenever there is any indication of passion and prejudice. Nor has any court ever held that, as a matter of due process, remittitur can never blanch a stain of passion and prejudice from a verdict, however visible that stain may be.

One approach this Court has taken to determining whether a particular practice accords with due process is to determine whether the practice was followed in 1868, which marks the "crucial time" for making that assessment as it is the year of the Fourteenth Amendment's ratification. *See Burnham v. Sup. Ct. of Calif.*, 495 U.S. 604, 611 (1990).

Remittitur as a remedy for excessive damages dates back to the English common law. *See Breadmore v. Carrington*, 95 Eng. Rep. 790 (K.B. 1764). As employed here, remittitur came into vogue as an alternative to a new trial, utilized to avoid the cost and delay that a new trial would entail. Justice Joseph Story is credited with introducing remittitur into American law in *Blunt v. Little*, 3 F. Cas. 760 (C.C.D Mass. 1822) (No. 1,578). There, as here, the defendant asserted that the jury's damages were excessive and thus merited a new trial. Justice Story wrote, "if it should clearly appear that the jury have committed a gross error, or have acted from improper motives, or have given damages excessive in relation to the person or the injury, it is as much the duty of the court to interfere, to prevent the wrong, as in any other case." *Id.* at 761-62. Still, he added, "it is reasonable, that the cause should be submitted to another jury, unless the plaintiff is willing to remit $500 of his damages. If he does, the court ought not to interfere farther." *Id.* at 762.

American law has remained the same since *Blunt*. Consequently, no long history supports supplanting the option of remittitur with a rigid requirement of a new trial whenever supposed passion and prejudice can be assumed from an excessive verdict, and '[t]he mere novelty of such a claim is reason enough to doubt that 'substantive due process' sustains it.'" *Dist. Attorney's Office for the Third Judicial Dist. v. Osborne*, 129 S. Ct. 2308 (2009) (quoting *Reno v. Flores*, 507 U.S. 292, 303 (1993).

Were Wyeth's understanding of due process the law, every denial of a motion for new trial—motions that mechanically allege some measure of "passion and prejudice"—would join a claim of constitutional error reviewable to this Court from a state high court. The rule's sweep, moreover, cannot easily be contained, "because guideposts for responsible decisionmaking in this unchartered area are scarce and open-ended." *Collins v. Harker Heights*, 503 U.S. 115, 125 (1992). Determining "constitutionally proper" levels of passion and prejudice (by distinguishing between that which demonstrates the jury abandoned neutrality and that which does not) has never been this Court's role, and should not be. *Cf. BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 602 (1996) (Scalia, J., dissenting).

IV. THERE IS NO LEGAL CONFLICT TO RESOLVE OVER THE PROPER RATIO BETWEEN SUBSTANTIAL COMPENSATORY AWARDS AND PUNITIVE DAMAGES

Wyeth claims that "lower courts are struggling" over whether "1:1 is a strict limit" on

punitive damages when the compensatory damages awarded are "substantial." Pet. 30. To assert that novel proposition, Wyeth avers that this Court established a rigid 1:1 ratio ceiling as a constitutional maximum, Pet. at 19, relying on language in *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 425 (2003) and treating *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 501, 514 (2008), as confirming that ratio as a "constitutional upper limit." Pet. 30. Neither decision establishes that doctrinaire approach to cases such as this one.

In advancing its unjustified claim of a strict constitutional 1:1 maximum, Wyeth manufactures a mathematical bright-line straitjacket out of precedential cloth that this Court has repeatedly, categorically, and wisely declared cannot be woven together. *See State Farm*, 538 U.S. at 424-25 ("[w]e have been reluctant to identify concrete constitutional limits on the ratio between harm, or potential harm, to the plaintiff and the punitive damages award. We decline again to impose a bright line ratio which a punitive damages award cannot exceed.") (emphasis added; citations omitted). *See also BMW*, 517 U.S. at 582 ("[W]e have consistently rejected the notion that the constitutional line is marked by a simple mathematical formula"); *Pac. Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 18 (1991) ("We need not, and indeed we cannot, draw a mathematical bright line between the constitutionally acceptable and the constitutionally unacceptable.").

In fact, the same paragraph in *State Farm* that suggests a 1:1 ratio is "perhaps" appropriate when the compensatory award is "substantial" reiterates that "there are no rigid benchmarks that a

punitive damages award may not surpass" and that "[t]he precise award in any case, of course, must be based upon the facts and circumstances of the defendant's conduct and the harm to the plaintiff." *State Farm*, 538 U.S. at 425.

Exxon Shipping did not change this constitutional construct. There, this Court recognized that particularly reprehensible misconduct warrants a larger punitive damage judgment. While this Court characterized Exxon's misconduct as mere "recklessness," 554 U.S. at 510 n.23, it also found that cases involving "exceptional blameworthiness," properly reside higher on the "punishable spectrum" and thus merit larger awards. *Id.* at 513.

This Court also took pains to emphasize in *Exxon Shipping* that it was not engaged in a due-process review of the punitive award, but instead its decision was an "exercise of federal maritime common law authority." 554 U.S. at 502. This Court further acknowledged that the exercise of that authority permits "more rigorous standards than the constitutional limit" on permissible punitive damage awards. *Id.* at 506. Because this case does not involve maritime law, *Exxon Shipping's* use of a 1:1 ratio has no application here.

Rather than set out some artificial ratio as the defining limit on punitive damages, the one constant in this Court's jurisprudence is an insistence that an appropriate punitive damage award reflect "'the enormity of the offense.'" *BMW*, 517 U.S. at 575 (1996) (quoting *Day v. Woodworth*, 54 U.S. (13 How.) 363, 371 (1851)). It is *that* proportionality principle that is "'deeply rooted" in our jurisprudence. *Id.* at 575 n.24 (citation omitted). Thus, this Court has

emphasized that the "'most important indicium of the reasonableness of a punitive damages award is the degree of reprehensibility of the defendant's conduct.'" *State Farm*, 538 U.S. at 419 (citation omitted). Examining a punitive damage award for gross excessiveness is a process of judicial review, not an exercise in elementary-school mathematics.

Here, as the Nevada Supreme Court established, the misconduct was not merely economic, but physical and potentially lethal. Wyeth's misconduct evinced an indifference to or a reckless disregard of the health or safety of others. It was intentional and not mere accident. And, it involved repeated actions on the company's part, as part of a concerted campaign over more than two decades to maintain its financial success. *See, e.g.*, Pet. App. 37a-39a. Thus, it involved many of the aggravating factors this Court recognizes as meriting larger punitive damages. *See State Farm*, 538 U.S. at 419.

Wyeth also calls this case "an ideal vehicle in which to address the question" of whether the Due Process Clause imposes a strict 1:1 ratio limit. Pet. 30. Even if this Court were inclined to disabuse the lower courts of the idea that a mandatory 1:1 ratio exists regardless of the egregiousness of the misconduct, which, of course, is not Wyeth's objective, this is a particularly inappropriate case for that exercise of this Court's discretion on this issue. First, the ratio between punitive and compensatory

damages in this matter is 1.56:1, hardly a difference sufficient to warrant this Court's consideration.[10]

Second, granting review in this case would encourage every defendant against whom punitive damages are awarded to treat as *de rigueur* a petition for certiorari whenever punitive damages do not strictly conform to their preferred ratio limit.

Finally, because Wyeth premises its claim of conflict on different absolute figures used by courts to determine what constitutes a "substantial" compensatory damage figure, Pet. 19, they seek an absurd determination by this Court of an absolute dollar threshold that would trigger the imposition of a strict 1:1 ratio, in essence a plea for the very bright-line rule that this Court has repeatedly and properly eschewed. The vast majority of courts have wisely not focused on dollar amounts *per se*, but instead have faithfully employed this Court's instruction that "[t]he precise award in any case, of course, must be based upon the facts and circumstances of the defendant's conduct and the harm to the plaintiff." *State Farm*, 538 U.S. at 425.

This is true of the courts Wyeth cites to establish a supposed conflict. Thus, instead of adhering to a 1:1 ratio as a strict limit, the Eighth Circuit adopted a 1:1 ratio in *Williams v. ConAgra Poultry Co.*, 378 F.3d 790, 799 (8th Cir. 2004), cited at Pet. 20, because it found that "$600,000 to compensate [plaintiff] for his harassment . . . is a lot of money." Thus, the substantiality of the

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[10] It is also well within the 3:1 ratio set by Nevada law. Pet. App. 40a (citing NRS 42.005(1)(a)).

compensatory damages was a function of its size relative to the injury to the plaintiff and the misconduct committed. Similarly, in the First Circuit, a 1.1 ratio was deemed a limit where the misconduct was reprehensible but not "particularly egregious" and the $35,000 compensatory damages judgment "amply compensate[d plaintiff] for the mental distress resulting from his confrontation with the Mayor." *Mendez-Matos v. Guaynabo*, 557 F.3d 36, 54, 55 (1st Cir. 2009), cited at Pet 20.

The Sixth Circuit also has employed that type of contextual analysis. Thus, *Bridgeport Music, Inc. v. Justin Combs Publ'n*, 507 F.3d 470 (6th Cir. 2007), held that a compensatory damages award of $366,939, which contained a substantial punitive element, combined with a low level of reprehensibility, could not sustain a $3.5 million punitive damage award, and remanded the punitive damages for "a ratio of closer to 1.1 or 2.1." *Id* at 490. Petitioner holds up another Sixth Circuit case, *Bach v. First Union Nat'l Bank*, 486 F.3d 150 (6th Cir. 2007), *see* Pet. 19-20, in support of its argument for slavish adherence to the 1:1 ratio it favors, even though the subsequent decision in *Bridgeport Music* held 2.1 would satisfy due process under that set of facts. Still, the *Bach* Court makes plain that its application of a 1:1 limit was not a general rule. It instead announced that it would "be wary of any attempt to graft our ruling here onto another set of facts." *Id.* at 156 Thus, like all courts considering the question of the due process limit on any punitive damage award, the *Bach* Court declared that "[a]scertaining the constitutionally correct amount of punitive damages in a given case is a highly fact-intensive exercise, and the facts before us drive our conclusion in this case." *Id.*

The lower courts, including those Wyeth wrongly claims follow a strict 1:1 limit, understand their obligation to examine the specific facts and circumstances and carry out that task without the confusion imagined by Petitioners. *See, e.g., Jurinko v. Med. Protective Co.*, 305 Fed. Appx. 13, 28 (3d Cir. 2008) (finding mere economic harm and not particularly egregious misconduct to justify a 1:1 ratio), cited at Pet. 20-21; *Roby v. McKesson Corp.*, 219 P.3d 749, 769 (Cal. 2009) (finding misconduct "at the low end of the range of wrongdoing" and supporting only a 1:1 ratio), cited at Pet. 21.

In contrast, these three women were grieviously injured and disfigured as a result of Wyeth's multi-decade egregious misconduct in creating an unjustified confidence in the safety of its drug. The facts of their cases were reviewed in depth by the lower courts in concluding the punitive damages were not excessive. There are no grounds that warrant review by this Court.

V. THERE IS NO DIVISION OF AUTHORITY REGARDING WHETHER THE DUE PROCESS CLAUSE BARS AN AWARD OF PUNITIVE DAMAGES WHERE A MANUFACTURER HAS COMPLIED WITH MINIMUM FEDERAL STANDARDS

The Due Process Clause imposes substantive limits on the broad discretion that States possess with respect to the imposition of punitive damages. *Cooper Industries*, 532 U.S. at 433. These limits, however, have never precluded a determination of reprehensibility based solely on regulatory compliance, as Wyeth suggests. Pet. 27. Case law establishes that regulatory compliance does not bar

the imposition of punitive damages where the regulatory standards lack preemptive effect. Moreover, here, there was substantial evidence that the FDA repeatedly admonished Wyeth for its marketing conduct and requested additional studies for over two decades, studies Wyeth refused to conduct. *See* 3, 9 *supra*.

In fact, Wyeth's theory that compliance should "constitute compelling evidence" against punitive damages, Pet. 27, was addressed in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984). There, this Court held that a federal statute did not preclude Oklahoma from awarding punitive damages in a case in which the alleged tortfeasors had substantially complied with a federal regulatory scheme. *Id.* at 258. It then remanded the case for consideration of whether substantial compliance with a regulatory scheme bars the award of punitive damages as a *matter of Oklahoma law*, and whether "the amount of the punitive damages award was excessive." *Id.*; *see* 769 F.2d 1451, 1457 (10th Cir. 1985) (deciding, on remand, that Oklahoma law does not categorically bar punitive damages based on substantial compliance). Nevada has already answered that question by upholding the punitive award here.

States undoubtedly have the authority to determine what value to accord a manufacturer's compliance with federal regulations in products liability actions. *See* American Law Institute, Restatement (Third) of Torts: Prods. Liab. § 4 (1998). *See also, e.g., Schultz v. Ford Motor Co.*, 857 N.E.2d 977, 988 (Ind. 2006) (recognizing state authority "to place some particular value upon compliance with federal safety standards"). Indeed, this Court has repeatedly recognized that "where state law provides

the basis of decision, the propriety of an award of punitive damages for the conduct in question, and the factors the jury may consider in determining their amount, are questions of state law." *Browning Ferris Indus. of Vt., Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 278 (1989). After all, a constitutionally valid award is one "supported by the State's interest in protecting its own consumers and its own economy." *BMW*, 517 U.S. at 572.

The laws of several states treat compliance with federal regulations or industry custom as rebuttable evidence that a manufacturer was not recklessly indifferent to potential harm, but nevertheless allow punitive verdicts if defendant's knowledge of the potential harm establishes reckless conduct that warrants punitive damages. *See, e.g.*, *O'Gilvie v. Int'l Playtex, Inc.*, 821 F.2d 1438, 1446 (10th Cir. 1987), *cert. denied*, 486 U.S. 1032 (1988) (Kansas law) ("[C]ompliance with the FDA regulations does not preclude punitive damages when there is evidence sufficient to support a finding of reckless indifference to consumer safety."), *Dorsey v. Honda Motor Co.*, 655 F.2d 650, 656 (5th Cir. 1981) (Florida law) ("[C]ompliance with [federal Motor Vehicle Safety Act Standards], which were far from comprehensive, [did not] preclude[ ] any finding of recklessness"); *Brown by Brown v. Stone Mfg. Co., Inc.*, 660 F. Supp. 454 (S.D. Miss. 1986) (Mississippi law) (compliance with federal flammability standards not conclusive on issue of whether fabric was unreasonably dangerous); *General Motors Corp. v. Moseley*, 447 S.E.2d 302, 311 (Ga. Ct. App. 1994) (rejecting argument that compliance with FMVSS 301 "precludes an award of punitive damages where . . . there is other evidence showing culpable behavior").

The record reveals that Wyeth "was negligent in failing to conduct appropriate studies on breast cancer and that it concealed material facts about its products' safety." Pet. App. 34a, 38a Moreover, as studies established the dangers its hormone therapy drug created, "Wyeth sought to downplay the studies' results and divert attention from the information." *Id.* Wyeth financed and manipulated scientific studies and sponsored medical articles to downplay the risk of cancer while promoting unproven benefits. Pet. App. 30a Plainly, Wyeth's reckless indifference to consumer safety was well-established.

A defendant who pursues a course of ongoing, deliberate misconduct, as Wyeth did here, has more than "fair notice" of the possibility of a substantial punitive damage award. In view of this record, Wyeth's conduct was unquestionably reprehensible, supports the reduced award determined by the Nevada courts, and does not merit exercise of this Court's discretion to review the issue.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted.

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